

Remarks

By this amendment, claims 1, 2, 4, and 5 are amended. The amendments are made to even more clearly define the claimed invention and do not add new matter. Support for the amendments to claims 1, 2, 4, and 5 is found, for example, at page 9, lines 27-29, to page 10, line 1, of the instant specification.

Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1-8 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirements.

Initially, Applicants note that the Examiner construed the claims to broadly encompass any nucleotide sequence capable of enhancing gene expression in motor and/or sensory neurons, due to the recitation of “sequences derived...by deletion, substitution or addition of one or more nucleotides.” Applicants note that the claims have been amended to recite “deletion, substitution, or addition of one to thirty nucleotides and capable of enhancing gene expression efficiency in motor neurons.” Applicants respectfully note that the claim, as amended, no longer read on any sequence with the claimed function. As amended, the claims are limited to the sequence claimed with up to 30 deletions, substitution or additions. Applicants note that this is fewer than 5% of the bases in the sequence.

The Examiner asserts that specification does not demonstrate that the sequences provided in Examples 1-4 would “drive transcription in any or all motor or sensory neuronal cells” as recited in the claims. Furthermore, the Examiner argues that the specification does not sufficiently disclose common attributes or features among the

claimed sequences necessary to define the claimed genus of nucleic acid sequences capable of driving transcription in any or all motor or sensory neuronal cells.

Applicants respectfully disagree. Applicants note that the specification clearly describes the common features or areas of homology between SEQ IDs 1-6 (see, e.g., page 10, lines 2-20, in the specification). The specification indicates that

[t]he region between nucleotides 235 and 560 of SEQ ID NO: 1, the region between nucleotides 204 and 528 of SEQ ID NO: 2, the region between nucleotides 206 and 530 of SEQ ID NO: 3, and the region between nucleotides 211 and 555 of SEQ ID NO: 4 are highly homologous to one another and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 1 to 4 **contribute to functions of enhancers for improving gene expression efficiency in motor neurons**. The region between nucleotides 378 and 553 of SEQ ID NO: 5 and the region between nucleotides 178 and 353 of SEQ ID NO: 6 are highly homologous to each other and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 5 and 6 **contribute to functions of enhancers for improving gene expression efficiency** in sensory neurons and/or in motor neurons that extend axons ventrally. (emphasis added)

The specification clearly asserts that these areas of homology “function as enhancers for improving gene expression efficiency in motor neurons,” thereby establishing a common feature with an associated common function among these sequences. Thus, one skilled in the art would appreciate the common structural features of the claimed genus of sequences, and would be convinced that the Applicants were indeed in possession of the claimed invention at the time of filing. Accordingly, Applicants submit that that the specification sufficiently describes the common structural features that the specification sufficiently defines the function recited in the claims, thereby clearly defining the claimed genus of sequences.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action rejects claims 1-8 under 35 U.S.C. § 102(b) as being anticipated by Meng et al. (Promoter Analysis in Living Zebrafish Embryos Identifies a Cis-Acting Motif Required for Neuronal Expression of GATA-2, hereinafter “MENG”). Claims 1-8 are also rejected as being anticipated by Higashijima et al. (Visualization of Cranial Motor Neurons in live Transgenic Zebrafish Expressing Green Fluorescent Protein Under the Control of the Islet-1 Promoter/Enhancer, J. Neuroscience, 2000, 20(1): 206-18, hereinafter “HIGASHIJIMA”).

Although the sequences disclosed in MENG and HIGASHIJIMA are not identical to the claimed sequences, the Examiner construed the claims to encompass any nucleotide sequence derived from SEQ ID NOs: 1- 4 by deletion, substitution, or addition of one or more nucleotides. The Examiner asserts that the claims include sequences derived by “the substitution of all but a single nucleotide from the SEQ IDs listed for an entirely different sequence.”

However, in light of the above amendments, Applicants respectfully submit that the cited publication do not disclose the sequences recited in claims 1-8. MENG discloses a 31-bp segment which is believed to enhance gene expression in motor neurons (MENG, Figure 2). HIGASHIJIMA discloses two 15 kb fragments which are believed to drive gene expression in branchiomotor neuron and trigeminal ganglion cells (see Figure 1(d), CM and SS sequence regions).

The claims require “DNA consisting of nucleotide sequences derived from SEQ ID NOs: 1- 4 by deletion, substitution, or addition of one to thirty nucleotides and capable of enhancing gene expression efficiency in motor neurons.” Accordingly, the sequences in MENG and HIGASHIJIMA do not anticipate the approximately 800-bp

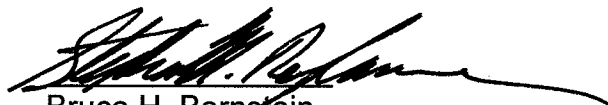
sequences recited in claim 1 (and the approximately 225-bp sequences recited in claims 2, 4, and 5).

For these reasons, Applicants submit that the cited publications do not disclose all of the elements of the claimed invention, and respectfully request that the rejections be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all outstanding rejections, and an indication of the allowability of all claims pending in the present application in due course. Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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